Subject Matter Code: C-05b Lead Aquatic Life

Comment ID: CTR-020-013
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-05b Lead Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

2. Lead

The 1984 lead criteria establishes very stringent chronic criteria due to an artifact of EPA's criteria calculation procedure - where inadequate data are available, a lower criteria is calculated. Thus, even where it is apparent that less restrictive criteria should be developed, the calculation procedures produce a lower criteria. This anomaly of criteria calculation could have been rectified by updating the criteria to add additional organisms that were tested since the 1984 Lead Criteria Document was published. Unfortunately, EPA failed to update the lead chronic water quality criteria which would have increased the chronic value from about 1.5 ppb to 15 ppb. This update has been acknowledged by EPA Duluth representatives in a number of public forums as acceptable, and it was approved for the Delaware River Basin Commission, a quasi-federal entity in 1996 (Exhibit 9). EPA's failure to update the lead database for the CTR is arbitrary and capricious and needs to be corrected

(a) The Technical Basis for EPA's Lead Criteria is Flawed

EPA criteria for lead were first published in 1980 and revised in 1984. The database from which the criteria were derived is very limited. EPA assessed only ten freshwater species and eleven saltwater species. Consequently, the data used to develop the lead criteria do not meet the minimum data requirements set forth in EPA's guidelines. (*41) In addition, the analytical methodology (acid soluble metal) used to assess lead concentration in the toxicity tests used to develop the criteria was a rigorous digestion that measured non-toxic, as well as toxic, forms of the metal.

Because the tests used to develop the lead criteria measured non-toxic forms of metal, and lead salts tend to form carbonates and precipitate readily from solution, the criteria overestimated the toxic fraction of lead. Thus, the lead criteria are very conservative. In addition, statistical deficiencies in the underlying data base render the lead criteria significantly more uncertain thanother criteria derived using the requisite data. As a result, some states have deferred adoption of EPA's lead criteria; others have adopted

more appropriate lead standards that are scientifically supported. North Carolina, for example, adopted a 25 ug/l lead standard (as total recoverable) because:

We believe that a standard based on an acid-soluble equivalent value of 1.3 ug/l Pb is extremely and unnecessarily overly protective, especially when considering the vast differences in Pb concentration that can be measured from the same sample, as shown by EPA's data. Since these values can vary as much as 50-75 fold for Pb according to EPA's data, implementing a standard of 25 ug/l measured as total recoverable metal which is less than 20 times higher than the acid-soluble criterion of 1.3 ug/l) is sufficiently conservative and technically sound... (*42)

The geometric mean for water effect ratios reported for lead using C. dubia and fathead minnows are consistently greater than five (5), which confirms a reduction in lead toxicity in natural waters by a factor of five relative to laboratory water of minimal complexing ability. (*43) This is not surprising since lead is readily complexed by inorganic and organic ligands in natural waters. (*44) Pagenkopf reported that relatively low concentrations of humic acids readily detoxify lead:

If there is 1 mg/liter humic acid (HA) in the water with an effective gram formula weight of 1000, a sizable amount of lead could be complexed. With these conditions the HA concentration would be 10E-6M, and if the 108 stability constant were applicable, essentially all of the humic acid would complex PbE+2. This would raise the total nontoxic species concentration and in fact could cause a shift from apparent toxicity to nontoxicity. (*45)

Given the abundance of complexing agents in biologically treated effluents and storm waters, a dissolved lead standard based on EPA's criteria is overly conservative.

(b) Conclusions With Respect to Lead

EPA should withdraw the proposed lead standard as unnecessarily restrictive and recalculate the criteria to reflect the additional studies conducted since the criteria were issued. Given the prevalence of lead in virtually all municipal effluents and storm waters, a minor change in the lead criteria will significantly affect treatment requirements. EPA should not apply the lead chronic criteria to storm waters where elevated TOC levels are prevalent and will detoxify the metal present.

(*41) See National Guidelines.

(*42) Letter from North Carolina DEHNR to EPA Region IV (January 23, 1990) (Exhibit 7).

(*43) See, Hall, Scott, et al. "The Use of Stream Side Macrocosms in the Evaluation of Copper, Lead and Zinc Effects on Acidic Stream Biota in Support of Deriving Site-Specific Water Quality Criteria." See also, Brungs, W. A. et al. "Synopsis of Water-Effects Ratios for Heavy Metals as Derived for Site-Specific Water Quality Criteria" (March 1992).

(*44) EPA Lead Criteria Document at 3.

(*45) Pagenkopf, Gordon K. "Metal Ion Speciation and Toxicity in Aquatic Systems, in Concepts in Metal Ion Toxicity." G.K Pagenkopf, H. Sigel, eds., at 113.

Response to: CTR-020-013

Although EPA agrees that the freshwater lead data set is less diverse by one taxon than the Aquatic Guidelines call for, EPA is retaining the criteria in the rule. EPA does not believe that the decreased taxonomic diversity in the data set is by itself a substantial shortcoming that would invalidate the criterion.

The comment about statistical deficiencies is not sufficiently specific for EPA to be able to identify to what the comment refers.

EPA is addressing the issue on bioavailability of different forms of lead (that is, the presence of "non-toxic" forms of lead) through expressing the criterion as dissolved lead and as function of a site-specific Water-Effect Ratio.

Subject Matter Code: C-06b Chromium Aquatic Life

Comment ID: CTR-061-013
Comment Author: G. Fred Lee & Associates
Document Type: Academia
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-06b Chromium Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Page 42168, third column, near the bottom, states, "However, EPA believes that it is appropriate to propose criteria in this rule based on the most recent data." Following that statement is a table (located on the bottom of page 42168 and top of 42169) in which the proposed freshwater criteria (CMC) for Cr VI is 16 ug/L. That table also lists the CCC for Cr VI as 11 ug/L. I have reviewed the literature on Cr VI toxicity (see attached "Chromium Speciation: Key to Reliable Control of Chromium Toxicity to Aquatic Life ") and find that 11 ug/L will not protect zooplankton from toxicity. There is substantial reliable data in the literature which show that Cr VI is toxic to zooplankton at 0.5 ug/L. This situation should have been discussed in the proposed CTR so regulatory agencies, the regulated community and the public learn that an 11 ug/L Cr VI criterion will not prevent zooplankton toxicity and could thereby violate the narrative toxicity standard of no discharge of toxic chemicals in toxic amounts. The CTR should also discuss the fact that in many ambient water systems Cr III (which is allowed to be discharged at 50 ug/L) can convert to Cr VI resulting in concentrations of Cr VI above those that are known to be toxic to zooplankton.

Response to: CTR-061-013

EPA does not agree that the 11 ug/L criterion will not protect zooplankton from toxicity. EPA believes its criterion for chromium is adequately protective. EPA has examined the quotation appearing in the submitted document "Chromium Speciation: Key to Reliable Control of Chromium Toxicity to Aquatic Life". EPA believes that the comment's Elnabarawy et al. (1986) citation refers to those authors' data published in Environmental Toxicology and Chemistry (Vol 5, pp. 393-398), and has examined that reference.

This material dealt with additional toxicity testing data rather than the data EPA used to derive the criterion. The material does not have data on previously untested species. Consequently, even if EPA were to include the Elnabarawy et al. (1986) data, then the results would be averaged with other study results for the same species, in order to obtain new Genus Mean Acute Values and Acute-Chronic Ratios, and recalculate the CMC and CCC.

Furthermore, even if the Elnabarawy et al. (1986) data were acceptable and included in a new criteria derivation, under no circumstances would EPA's criteria derivation procedure allow setting the criterion to the lowest test result (0.5 ug/L) among replicate tests. The averaging of test results prevents the criteria from being unnecessarily influenced by experimental errors. Consequently, even if EPA were to update the criterion for this rule, it cannot be predicted whether the entire body of new data (as opposed to the lowest test results therein) would cause the criterion to go up or down, or leave it essentially unchanged.

An additional problem is that there is doubt as to whether EPA could judge the Elnabarawy (1986) data to be acceptable. Although all or nearly all treatment concentrations for Ceriodaphnia reticulata and Daphnia magna had reproductive success that was statistically significantly lower than the control response, essentially all treatments had the same response, only slightly lower than the control, despite 100 fold differences in concentration.

Data from Elnabarawy et al. (1986)

	Average number of young per adult			Adult survival percentage		
Cr (VI) ug/L	D.magna	D.pulex	C.reticulata	D.magna	D.pulex	C.reticulata
Control	85	53	23	100	100	100
0.5	76	44	16*	100	100	100
1.5	69*	44	16*	100	80	100
5.0	71*	45	16*	100	80	100
15.0	71*	45	14*	60	80	100
50.0	47*	42	14*	0*	50	100

* Significantly different from control, p less than or equal to 0.05.

The expected behavior for this experiment would be a sigmoidal concentration-response curve (in this case a backwards "S" shape) with the low concentrations displaying similar responses to the control, and the higher concentrations with more or less progressively lower reproductive or survival success. The character of Elnabarawy et al. (1986) data suggest that the somewhat depressed reproductive success for D. magna between 0.5 and 15.0 ug/L and for C. reticulata between 0.5 and 50.0 ug/L may not due to chromium.

Consequently, EPA cannot accept the comment's contention that new evidence has demonstrated that the CCC specified in the rule, 11 ug/L, would not adequately protect aquatic life uses.

With regard to the conversion of chromium (III) to chromium (VI), EPA does not agree that the rule, in setting forth criteria concentrations, needs any provision for interconversion of oxidation states. EPA believes that site-specific fate considerations are best handled during the waste load allocation or permitting processes, not during the state-wide standards setting process.

Finally it should be noted that in analyzing the toxicity tests underlying the CMC and CCC for chromium (III), EPA assumed that none of the chromium (III) was converted to chromium (VI). To the degree (if any) that chromium (III) was oxidizing to chromium (VI) in the underlying toxicity tests, the chromium (III) criterion would already account for that degree of conversion.

Subject Matter Code: C-07b Cyanide Aquatic Life

Comment ID: CTR-058-013
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-07b Cyanide Aquatic Life
References:
Attachments? Y
CROSS REFERENCES

Comment: Marine Cyanide Criteria. In 1996 WSPA submitted to the Washington Department of Ecology three reports in support of developing site-specific water quality criteria for cyanide. These reports were:

* Acute Toxicity of Cyanide to Two Species of West Coast Crabs, Cancer productus and Cancer gracilis;

* Literature Review of Cyanide Toxicity Data * Range and Distribution of Cancer branneri

These studies support an acute criterion of 9.4 ug/L and a chronic criterion of 1.5 ug/L using the EPA calculation procedures with data for C. irroratus being replaced by the Genus Mean Acute Value for four West Coast Cancer species. An acute to chronic ratio of 6.458 was used based on a recommendation by Mark Hicks of the Department of Ecology.

WSPA incorporates these studies into the record by reference (we will transmit the studies under separate cover) and urges EPA to review these data and support site specific marine cyanide criteria of 9.4 ug/L and 1.5 ug/L for California as well.

Response to: CTR-058-013

EPA agrees with incorporating the data generated for Cancer magister, C. oregonensis, C. productus, and C. gracilis into the data set underlying the cyanide saltwater criterion. The data for all tested species in genus Cancer are then as follows:

C. magister: LC50s 51.24 & 91.5 ug/L; SMAV 68.47 ug/L
C. oregonensis: LC50s 111.3 & 154.1 ug/L; SMAV 131.0 ug/L
C. productus: LC50 219 ug/L; SMAV 219 ug/L
C. gracilis: LC50 153 & 135 ug/L; SMAV 143.7 ug/L
C. irroratus: LC50s 4.2 & 5.7 ug/L; SMAV 4.893 ug/L

Within a genus, such as Cancer, in situations where toxicity data are available for some of the species, but not all of the species found in a state, data on tested resident species and data on tested non-resident species are both used to represent the untested species, when calculating site- or state-specific standards.

In contrast, for the State of Washington, where all resident Cancer species were tested (that is, C. magister, C. oregonensis, C. productus, and C. gracilis), EPA agreed that the GMAV for Cancer could be

recalculated after excluding C. irroratus, because (a) C. irroratus did not occur in Washington, and (b) it could not represent any untested Cancer species in that state since all resident Cancer species had been tested.

However, EPA has no data on the occurrence of Cancer species in California. Nor did the commenter submit any such data. As a result, EPA is unable to make the determination that C. irroratus could not represent any untested Cancer species occurring in California. That is, with the information available, EPA is not able to determine whether some Cancer species other than the above five occurs in California. If such Cancer untested species did occur in California, then C. irroratus would be considered as likely as any of the others above to represent the sensitivity of the untested Cancer species, and would thus not be deleted from the data set. Consequently, for this rule, the cyanide criterion was determined by considering all five of the above species.

The SMAV for C. irroratus is more than an order of magnitude less that the LC50 for any other species in the genus Cancer. The tests on C. irroratus were flow-through, measured tests at 20 degrees C. The tests on the other Cancer species were renewal, measured tests at 10 degrees C. EPA has not found any persuasive reason to believe the C. irroratus data to be in error. The observed difference between C. irroratus and the other Cancer species may be due to (a) genuine biological differences among species (although such large differences within a genus are not common), (b) reproducible differences stemming from different experimental conditions (flow-through test at 20degrees C versus renewal test at 10 degrees C), or (c) non-reproducible experimental variation.

The Aquatic Life Guidelines (the procedures EPA uses to derive criteria) discuss the situation where there are large differences among species in a genus. The Guidelines caution against taking a geometric mean of SMAVs when the values differ by more than a factor of 10, but do not precisely indicate what should be done in such cases. Generally, for other criteria included in the rule, when the SMAVs differed by more than a factor of 5, the GMAV was set equal to the lowest SMAV. When that is done for Cancer, the GMAV remains at 4.893 ug/L. The CMC and CCC thus remain unchanged from the proposed rule, both having the value of 1.0 ug/L.

Comment ID: CTR-092-012b
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-07b Cyanide Aquatic Life
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-03b

Comment: Validity Of Proposed Nickel And Cyanide Criteria On A Statewide Basis

Attachment 1 to this letter is a technical report entitled "Task Report 1: Update and Recalculation of the Freshwater and Saltwater Cyanide Criteria", dated November 5, 1996 and prepared by Tetra Tech, Inc. for the City of San Jose. Attachment 2 to this letter is a technical report entitled "Final Report Recalculation of the Nickel Criteria for South San Francisco Bay", dated November 1, 1995 and prepared

by Tetra Tech, Inc. for the City of San Jose. All of the attachments to this letter are incorporated as part of our comments and are being submitted for inclusion in the record for this rulemaking.

EPA has an obligation to consider the most current, scientifically defensible data in this rulemaking. EPA's obligations in this regard are particularly significant in light of its obligations under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C.A. 601 et seq.) to consider a full range of cost effective alternatives to promulgation of the proposed Rule.

Although the title of Attachments 1 and 2 suggest that the data submitted relates only to San Francisco Bay, the data in fact relates to the entire state of California, and indicates that lessstringent cyanide and nickel criteria than are proposed by the Rule would adequately protect water quality in California. Under the Executive Order 12866 and the Regulatory Flexibility Act, EPA should include consideration of the these less stringent criteria in its Economic Analysis.

Response to: CTR-092-012b

EPA does not agree that the nickel and cyanide site-specific criteria developed for South San Francisco Bay necessarily apply to the entire State of California. EPA has examined the two reports ("Final Report: Recalculation of the Nickel Criteria for South San Francisco Bay" and "Update and Recalculation of the Freshwater and Saltwater Cyanide Criteria") referenced in the comment, and could not find evidence that the analysis contained therein applies to or was intended to apply to the entire state. EPA is not claiming that it has evidence that the San Francisco Bay analysis is not valid in other parts of the state. However, because the comment provided no information to support its assertion that the cited data relate to the entire state, and because EPA has no information of its own to determine the occurrence of species in the state, EPA is not able to conclude that the South Bay analysis applies state wide. To adjust the nickel and cyanide criteria statewide, EPA would need a statewide analysis of the type done for South San Francisco Bay. These site-specific studies must first be reviewed and approved by State authorities; they may then come to approval. If approved, EPA would rescind the criteria for nickel and/or cyanide in the CTR for the South San Francisco Bay.

With respect to the commenter's suggestion that these studies should be considered in any costing analysis for the CTR under Executive Order (E.O.)12866 and the Regulatory Flexibility Act, EPA does not agree. EPA has made clear elsewhere in the record of the rule that these criteria are health-based and are not based on cost-benefit balancing. The E.O. 12866 is supplemental information that shows the indirect costs and benefits of CTR criteria; it is an indication of the magnitude of the costs and benefits of the resulting water quality standards implemented through the NPDES permit program. With respect to the RFA, EPA addresses this issue in the preamble to the final rule and elsewhere in the final record for the final rule.

[The remaining parts of the response were written by Region 9 and are not shown here because I do not have an electronic version of them. All issues with that portion of the response deal with regional matters outside the purview of the national program.]

Subject Matter Code: C-08a Arsenic Human Health

Comment ID: CTR-020-007
Comment Author: City of Stockton
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions. The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

3. Arsenic

Arsenic human health criteria have been deleted as not being based on reliable scientific information. (This action followed a petition for rulemaking to amend the NTR for Alaska.) In the preamble, EPA tries to promote use of a 5 ppb human health criteria which was never adopted by the state. The number routinely approved by the Agency for other states is 50 ppb. Based upon the Agency's recent discussion of the current scientific information regarding arsenic addressed in the modification of the National Toxics Rule for Alaska (62 Fed. Reg. 27707-27710), EPA should clarify that the 50 ppb drinking water objective is acceptable to meet all Clean Water Act requirements.

Response to: CTR-020-007

In the final rule, EPA is not promulgating human health criteria for arsenic. As stated in the preamble, EPA made the decision not to promulgate human health criteria in light of number of issues and uncertainties that have arisen concerning the effects of arsenic on human health. A discussion of these issues are contained in a document entitled "Issues Related to Health Risk of Arsenic" that is contained in the administrative record for this rule. EPA is currently completing a review of the risk assessment for arsenic in an effort to resolve these concerns.

Although the State did not adopt a human health criterion for arsenic, California has previously expressed its scientific and policy position by recommending the use of 5 ppb in providing human health protection. This value has been utilized by the State in implementing its narrative criteria. EPA expects that the State will continue to implement its narrative criteria to ensure that protections are in place for arsenic.

As the commenter noted, many states have adopted human health criteria for arsenic based on the maximum contaminant levels (MCL) under the Safe Drinking Water Act. In addition, many States have arsenic criteria in place that are based on EPA's existing Section 304(a) criteria guidance. As stated in EPA's December 12, 1988 guidance to states on complying with CWA Section 303(c)(2)(B) and in the Agency's policy on the use of Section 304(a) criteria and MCLs (published at 45 FR 79320, November

28, 1980), EPA encourages the use of MCLs for the protection of public water supplies. However, where fish consumption is an important activity in a waterbody, EPA recommends the use of the Section 304(a) criteria. EPA does not believe that any further clarification is needed.

Comment ID: CTR-030-003
Comment Author: Utility Water Act Group
Document Type: Trade Org./Assoc.
State of Origin: DC
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: C. EPA is Correct to Delay Promulgation of Human Health Criteria for Arsenic

Given the numerous uncertainties involved in developing scientifically defensible human health criteria for arsenic, UWAG supports EPA's decision to delay promulgation of such criteria in theCalifornia water quality standards. As noted in the preamble, those uncertainties include: (1) arsenic exposure evaluations, (2) metabolism and detoxification processes, (3) analytical methods, and (4) effects at low doses. 62 Fed.Reg. at 42,179, col. 1. EPA has prudently decided to await resolution of these uncertainties before promulgating additional arsenic human health criteria.

Response to: CTR-030-003

EPA acknowledges the numerous comments that support the Agency's decision not to promulgate human health criteria for arsenic in today's rule.

Comment ID: CTR-035-002c
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
G-05
G-04
G-09
K-01
C-24a

Comment: Second, we commend EPA for its inclusion in the CTR of several innovative and flexible

regulatory approaches, such as metals criteria expressed as dissolved rather than total recoverable concentrations, and the revised human health criterion for mercury. In addition, in light of the issues surrounding the human health criteria for arsenic we support EPA's decision not to promulgate human health criteria at this time. With respect to implementation issues discussed in the Preamble, we support EPA's policies and guidance regarding the application of mixing zones and dilution credits. the use of interim permit limits while Total Maximum Daily Loads (TMDLs) and other special studies are being performed, and EPA's guidance to Regional Water Quality Control Boards (RWQCBs) that they may use any of the methods described in EPA's guidance document on the use of translators. We also support EPA's proposal to create a rebuttable presumption for Water Effects Ratios (WERs), allowing the RWQCBs and SWRCB to develop site-specific WERs that can be approved by EPA during the NPDES permit approval process. We believe that this approach will help facilitate the development of appropriate site-specific adjustments for metals criteria.

Response to: CTR-035-002c

See response to CTR-030-003.

Comment ID: CTR-035-025
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42179 - Arsenic Human Health Criteria We support EPA's decision not to promulgate human health criteria for arsenic at this time. However, in light of the scientific uncertainties identified by EPA, we strongly recommend that EPA remove from the Preamble the recommendation that State permitting authorities use 5 ug/l in evaluating and interpreting the narrative water quality criteria, since EPA's own scientific judgment is that there is an insufficient basis for setting valid human health criteria at this time. Instead, as an interim measure, EPA should recommend that the maximum contaminant level (MCL) for arsenic of 50 ug/l be used by permit writers, as has been approved as the human health criterion for the State of Alaska.

Response to: CTR-035-025

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-041-005
Comment Author: Sacramento Reg Cnty Sanit Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97

Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Fourth, for arsenic, the District strongly supports EPA's recognition that human health criteria should not be proposed at this time. The District is aware of the confusion in issues and the uncertainties that have developed concerning the measurement of the health effects of arsenic, and consequently the District supports the Agency's review of risk assessments for arsenic before promulgating criteria in any more states. In light of this reasoning, the District recommends that EPA withdraw its final sentence in this discussion recommending that permitting authorities in California refer to the State's criterion level of 5 ug/l in interpreting and evaluating narrative water quality criteria.

Response to: CTR-041-005

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-045-007
Comment Author: Sausalito-Marin Sanitary Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: The District supports many of the items included in the proposed CTR:

EPA's decision not to promulgate human health criteria at this time in light of the issues surrounding human health criteria for arsenic.

Response to: CTR-045-007

See response to CTR-030-003.

Comment ID: CTR-056-004
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-08a Arsenic Human Health
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N

CROSS REFERENCES

Comment: Second, EBMUD would like to express to EPA it support for inclusion of:

* The decision NOT to promulgate human health criteria at this time for arsenic in light of uncertainty surrounding the human health effects of this element,

Response to: CTR-056-004

See response to CTR-030-003.

Comment ID: CTR-059-007
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Arsenic Human Health Criteria

We support EPA's decision not to promulgate human health criteria for arsenic at this time in light of the scientific uncertainties regarding the risks posed by arsenic in water. EPA currently has two different human health values for arsenic in water: 0.018 ug/L for the ambient water criterion and 5 0 ug/L for the drinking water maximum contaminant level (MCL). In its own decision document for arsenic(*2), EPA states that "Having two very different criteria for arsenic (0.018 ug/L ambient water v 50 ug/L in drinking water) to protect human health drinking water exposures is very confusing to the public. These different values have been difficult to explain, defend, and implement in EPA and State Programs." Based on this discussion, we strongly recommend that EPA remove from the Preamble the recommendation that State permitting authorities use 5 ug/l in evaluating and interpreting the narrative water quality criteria. Instead, as an interim measure, EPA should recommend that the MCL for arsenic of 50 ug/l be used by permit writers, as has been approved by EPA as the human health criterion for the State of Alaska.(*3)

(*2) U.S. Environmental Protection Agency, Decision Document for Arsenic. I.A.9.c Issues Related to Health Risk of Arsenic (no date).

(*3) 62 Federal Register 27707-27710 (May 21, 1997).

Response to: CTR-059-007

See response to CTR-030-003 and CTR-020-007.

Comment ID: CTR-060-004
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E SUPPORTS

EPA has included in the proposed CTR provisions which are reasonable and with which SDG&E supports. These include:

Delay of arsenic human health criteria

The preamble states that EPA has decided to not propose human health criteria for arsenic in this rule due to a number of issues and uncertainties concerning the health effects of arsenic (see 62 Fed. Reg. at 42179, Col. 1). SDG&E supports this decision because it is important to base criteria upon sound science. Adoption of the criteria should be delayed until the referenced issues and uncertainties are resolved.

Response to: CTR-060-004

See response to CTR-030-003.

Comment ID: CTR-066-009
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Our preliminary review of the CTR finds several areas that we believe are positive changes and will enhance the rulemaking. The areas that we support as now written are as follows:

* The decision not to promulgate human health criteria at this time in light of the issues surrounding the human health criteria for arsenic.

Response to: CTR-066-009

See response to CTR-030-003.

Comment ID: CTR-081-002g
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES G-04
C-24a
G-02
C-22
G-09
C-01a
G-05

Comment: * There are many aspects of the CTR that we support. These include: a) Application of interim limits while special studies are perfomed. b) Approach to water effect ratios for determining site specific criteria. c) Inclusion of provision for compliance schedules. However, this should be modified to allow inclusion of compliance schedules of up to 15 years in permits if deemed appropriate by Regional Boards. d) Metals criteria expressed as dissolved rather than total recoverable concentrations. e) EPA's guidance to Regional Boards regarding use of translators. f) EPA's proposal to create a rebuttal presumption for Water Effects Ratios, g) Revised human health criteria for mercury h) Decision to not promulgate human health criteria at this time in light of issues surrounding health criteria for arsenic. i) EPA's policies regarding application of mixing zones and dilution credits.

Response to: CTR-081-002g

See cross references in categories C-24a, G-02, C-22, G-09, C-01a, G-05.

See response to CTR-030-003.

Comment ID: CTR-085-010
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: On several aspects of the California Toxics Rule, the District is in agreement with CASA and SCAP comments:

* The EPA's decision not to promulgate human health criteria at this time in light of the issues surrounding the human health criteria for arsenic.

Response to: CTR-085-010

See response to CTR-030-003.

Comment ID: CTR-089-001c
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-08a Arsenic Human Health
References:
Attachments? N
CROSS REFERENCES C-22
C-01a
G-05
K-01
G-02
G-09

Comment: The draft California Toxics Rule (CTR) is clearly the product of substantial effort by USEPA staff, and we applaud this effort and its intent. On several issues of concern to public utilities, the CTR strikes a good balance between the need to promulgate standards and the need to base those standards on sound science. Examples include the use of dissolved concentrations rather than the total recoverable concentrations for metals, the deferral of human health criteria for arsenic until adequate information is available, and the revision of the human health criterion for mercury. We are also pleased with the CTR's guidance and flexibility, on mixing zones and dilution credits, total maximum daily loads (TMDLs), compliance schedules, and translators.

Response to: CTR-089-001c

See cross references in categories C-01a, G-05, K-01.

See response to CTR-030-003.

Subject Matter Code: C-09a Dioxin Human Health

Comment ID: CTR-002-006
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: EPA unscientifically rejects criteria for 16 dioxin-like chemicals that impair San Francisco Bay. The 16 dioxin compounds that are not controlled by EPA's proposed criteria cause 80% of dioxin-like toxicity in San Francisco Bay fish tests supporting the human health advisory noted above.(*20) Subtracting all 2,3,7,8-TCDD toxicity does not change these dioxin-like toxicity estimates enough to reverse the conclusions which support this advisory.(*20) (*16) Thus, these 16 compounds impair fishing uses in San Francisco Bay. A criterion which includes the 16 dioxins developed by the state was approved in EPA's prior technical review, and the discussion in EPA's proposal shows that EPA still believes this criterion is scientifically defensible. Therefore, EPA's rejection of a criterion it believes is scientifically sound renders EPA's refusal to include criteria needed to protect San Francisco Bay fishing from these 16 dioxin-like chemicals without any valid scientific support.

(*16) California Regional Water Quality Control Board, San Francisco Bay Region, 1995. Contaminant levels in fish tissue from San Francisco Bay. Final draft report. Excerpt including data from toxic pollutant analyses of fish tissue samples from S.F. Bay. December, 1994.

(*20) Comparison of dioxin-like toxicity equivalents in San Francisco Bay fish tissue: 2,3,7,8-TCDD v. seventeen 2,3,7,8-substituted dioxins and furans. Table using data from Attachment 16, and analysis by CBE.

Response to: CTR-002-006

A commenter suggests that the Agency not include dioxin (2,3,7,8-TCDD) in this rule, pending completion of its ongoing reassessment of risks associated with exposure to dioxin and related compounds. In a contrary view, other commenters suggest that the Agency promulgate criteria not only for dioxin, but for related compounds--to include toxicity equivalent factors (TEFs) for– polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans and co-planar polychlorinated biphenyls (PCBs). TEFs evaluate these related compounds as equivalent concentrations of 2,3,7,8-TCDD and are used as a method for capturing the total dose associated with environmental exposure to mixtures of dioxin and dioxin-like compounds.

In response to the first comment, EPA disagrees. EPA still views dioxin as an extremely serious health threat and, therefore, does not wish to delay further establishment of an ambient water quality criterion for California subject to this rule.

In order to base its regulatory decisions on the best available science, EPA periodically updates its

scientific assessment of the risk associated with exposure to environmental toxicants. In September of 1991 EPA's Office of Research and Development (ORD) began such a reassessment on the toxicology and exposure science of dioxin and related compounds. The scope of this reassessment effort has been much broader than previous dioxin assessments. Included in the dioxin reassessment effort are the identification and characterization of: dioxin sources; dioxin environmental fate and transport; pathways of human exposure; levels of and trends in human exposure; full assessment of cancer, and non-cancer toxic effects; development of quantitative dose response relationships for all the effects; and the characterization of risks posed by dioxin exposure. Once completed after a final, upcoming peer review, the reassessment will serve as the principal scientific and technical basis for EPA's future dioxin risk management policies and programs.

When the reassessment began, the Administrator of EPA directed that Agency actions move forward without change in substance or timing until the reassessment is completed (Memorandum of William K. Reilly, September 11, 1991 "Dioxin Regulatory Program"). This direction has not changed. EPA continues to rely upon its 1985 assessment and the cancer slope factor it describes as the technical basis for policy and regulation; this is the assessment of dioxin in place as of September 11, 1991.

Consistent with this direction, EPA knows of no compelling reason not to include dioxin in the rule at this time. Instead, EPA believes it is an appropriate public health step to apply the current dioxin criteria in this rule and consider the merits of revising the criterion applicable in this rule (and to all other states covered by the National Toxic Rule) once the entire dioxin reassessment is complete and EPA revises its dioxin criteria. In the National Toxics Rule, EPA noted that a number of factors (as discussed below) may change but that the resulting criterion might remain the same. These concerns were reflected in EPA's response to comments in the National Toxics Rule. "It is too early in the process of scientific reassessment to support major changes in either the substance or timing of regulatory decisions related to dioxin." 57 Fed. Reg. 60884. EPA notes further that this approach, with respect to the National Toxics Rule, was upheld by the U.S. District Court for the District of Columbia in American Forest & Paper Assn, Inc. v. U.S. Environmental Protection Agency, No. 93-cv-0694 slip op. at 14-16 (D. D.C. 1996); 1996 U.S. Dist. LEXIS 13230. Based on information currently available to the Agency, the dioxin limit promulgated today for 2,3,7,8- tetraclorodibenzo[p]dioxin remains in the range of scientific defensibility.

EPA has provided a leadership role in the adoption and application of TEFs and is generally supportive of their use for risk assessment and risk management. However, the expansion of water quality criteria to include the full range of dioxin-like compounds is only one of many issues that needs to be addressed in revising water quality criteria. From an EPA perspective, the public is best served by having all these factors considered simultaneously. For this full review of the dioxin Water Quality Criteria to be well founded in science, it needs the benefit of a completed, peer reviewed, reassessment. Reexamining the cancer slope factor for 2,3,7,8- tetraclorodibenzo[p]dioxin and TEFs are among many issues important to future water quality criteria, but are not the only issues. The reassessment also includes coverage of reproductive, developmental, neurotoxic and other effects as well as fundamental questions as to the mode of action by which dioxin causes all of its effects. These will be considered in a thorough revision of water quality criteria. Interim adjustments based on only some parts of the toxicology or quantitative assessment would not support coherence in the scientific work or policy development that underlie Agency action. There are a number of outstanding issues that could result in modification of the water quality criteria, including: expanding the criteria to all dioxin-like compounds; adopting a new cancer slope factor; considering non-cancer effects as well as cancer effects; taking into account background levels and exposure; adjusting fish consumption patterns; adjusting bioconcentration and bioavailability factors; and adopting new TEF values. Some of these factors could lead to strengthening the water quality criteria while others might support relaxation. It is presently unknown what the net effect of all these factors may have on revised dioxin criteria. EPA continues to believe that waiting for the final

peer review reassessment to be completed so that all of these issues can be addressed simultaneously, is preferable to a sequence of incremental revision to the criteria based on only a few of these concerns. Thus, until EPA completes this reassessment, when EPA promulgates water quality criteria for a State, EPA will not use this approach.

For the reasons discussed above, the Agency is promulgating an ambient water quality standard only for 2,3,7,8-TCDD. This action is consistent with Section 303(c)(2)(B) and the National Toxics Rule (57 Federal Register 60863-60864, December 22, 1992) based on EPA's 1984 Ambient Water Quality Criteria Document for Dioxin. California, however, may adopt criteria for other related compounds.

See also response to CTR-002-003 (Category C-24; Site-Specific Criteria).

Comment ID: CTR-016-008
Comment Author: San Francisco Bay RWQCB
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: Comments on the Proposed Dioxin Criteria

In the preamble, EPA states its support for California's use of Toxicity Equivalents (TEQ) in setting NPDES permit limits, yet proposes standards for only one type of dioxin. We have found that appropriate water quality protection requires consideration of all congeners because it is only through congener "fingerprints" that distinctions can be made between atmospheric deposition and wastewater sources. Most dioxins and furans are released to the environment through air emissions. In addition, EPA should also provide guidance for determining permit compliance for discharges dominated by higher chlorinated congeners given the slim data base that established the equivalent factors for these higher chlorinated congeners. Below are the reasons for these recommendations.

EPA is proposing standards for 2,3,7,8-tetrachlorinated dibenzo-p-dioxin (TCDD) that are consistent with the NTR and that are based on the 1984 criteria. The TEQ concept uses toxicity equivalency factors (TEF) to convert mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) to equivalent concentrations of 2,3,7,8-TCDD.

EPA states in the preamble:

"...The concept of TEQ and the use of the I-TEFs/89, as outlined in EPA's 1989 Interim Procedures, provided valuable guidance in using the 2,3,7,8-TCDD water quality criteria in setting National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits that are protective of human health for dioxin and dioxin-like compounds."

Discharge data from our region, which we have shared with EPA, show that applying this statement strictly would raise significant permit compliance issues for many wastewater point sources. Guidance

on an implementation strategy for dioxin is needed. We believe it is appropriate for EPA to provide this guidance because they have a broad multimedia understanding of the current state of knowledge about the major sources and fate of PCDD/PCDF.

Based on an extensive review of local and international scientific data, we have found that the major sources of dioxins to the environment are from emissions to air. However, the ultimate sink for PCDD/PCDF is the aquatic sediment. As a result, aquatic indicators such as fish tissue may show a problem regardless of the significance or insignificance of current wastewater point sources in that area.

In the San Francisco Bay area, we find that most of the PCDD/PCDF enters surface waters from storm water runoff. Another significant portion may come from direct deposition of PCDD/PCDF onto the bay surface from the ambient air. The sources to storm water are most likely from emissions to air and reservoir sources.

Considering this, control of the air emissions sources rather than controls through the NPDES permit program would appear to us to have the most impact on water quality. Of course, in certain areas where there is a significant point source such as paper and pulp mills, it may be prudent to control that source because of potential impacts on the local area.

In any case, because of the significance of air emission sources, EPA should provide an implementation strategy for regulating PCDD/PCDF using the TEQ approach.

On the issue of uncertainty of TEFs, we believe that, as part of the California Toxic Rule, EPA should provide guidance for determining permit compliance on samples dominated by hepta- and octa-CDDs and CDFs. We believe this is necessary because of the uncertainty of the TEF values for these congeners, and because of the dominance of these congeners in many of the discharge samples in our region.

According to EPA's 1989 Interim Procedures document, the data base for the TEFs for hepta- and octa-CDDs and CDFs are very slim. For octa-CDD and CDF specifically, EPA acknowledged in the document that the TEFs reflect the results of a single experiment. Permit violations triggered by TEFs that are based on a very slim data base concerns us. This concern is compounded by the fact that discharge and storm water sample data from our region show hepta- and octa-CDDs and CDFs account for 20 to 100% of the total TEQ of the samples.

Response to: CTR-016-008

See response to CTR-002-006.

Comment ID: CTR-035-024
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N

CROSS REFERENCES

Comment: p. 42178 -- 2,3,7,8-TCDD (Dioxin) Criteria We recommend that EPA not adopt criteria for dioxin at this time for the following reasons. First, we recommend that EPA is still completing the dioxin reassessment, and, similar to EPA's decision regarding the human health criteria for arsenic, we believe that EPA should defer adoption of the criteria at this time. Second, as pointed out elsewhere in these comments, we believe that there are fundamental problems in EPA's adopting criteria that are below detection limits and for which compliance costs cannot be properly determined. Third, use of dioxin has been banned, and therefore traditional control methods are unlikely to succeed in achieving meaningful reductions in dioxin levels in the ambient environment. Therefore, we urge EPA and the State to instead focus watershed management efforts on developing strategies for addressing dioxin issues (where dioxin is demonstrated to be causing water quality use impairment).

Response to: CTR-035-024

See response to CTR-002-006.

Comment ID: CTR-039-006
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: IV. EPA MUST LOWER THE PROPOSED 2,3,7,8 TCDD DIOXIN NUMBER IN ORDER TO ACCOUNT FOR THE ADDITIVE TOXICITY OF 16 OTHER DIOXIN CONGENERS

BayKeeper believes that the only appropriate water quality standard for dioxin is zero. That being said, the State of California's 1991 criteria for dioxin included all 17 dioxin compounds. EPA's rule purposes to establish a criteria for only one of those congeners - 2,3,7,8-TCDD. The State's 1991 rule applied toxicity equivalency factors ("TEFs") promoted but not promulgated by EPA in the proposed rule. The toxicity equivalency concept takes into account the additive toxicity of the congeners on each other and, as EPA appears to acknowledge, more likely protects human health for dioxin and dioxin-like compounds. Unfortunately, EPA once again defers to a non-existent state process to fill in the regulatory gap for the other 16 dioxin compounds. As is clear from the State of California's recently proposed implementation plan for EPA's proposed criteria, the State is not proposing to take EPA up on its offer to make the dioxin criteria truly protective by applying TEFs after the fact. Assuming that EPA insists on attempting to protect people from dioxin by only regulating one of the congeners, at a minimum, in order to account for the toxicity of 2,3,1,8-TCDD where a mixture of dioxins is present, EPA should reduce the proposed criteria of .014 pg/L to .0014 pg/L to account for additional toxicity resulting from the presence of other dioxins and consistent with the State's prior technical decision on dioxin.

Response to: CTR-039-006

See response to CTR-002-006.

Comment ID: CTR-053-003c
Comment Author: Heal the Bay
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-09a Dioxin Human Health
References: Letter CTR-053 incorporates by reference letter 6 and the comments on Dioxin, copper, and the compliance schedule from letter CTR-002
Attachments? N
CROSS REFERENCES C-01b
C-02b

Comment: In spite of our lack of detailed comments for specific criteria, we have concerns regarding any weakening of California's previously developed standards, particularly those for mercury and copper. Also, we question the absence of criteria for dioxin and dioxin-like compounds. In order to ensure these issues are considered in future improvements of the Rule, we incorporate by reference the comments of the Natural Resources Defense Council regarding mercury, and the comments of Communities for a Better Environment ("CBE") regarding dioxin compounds and copper.

Response to: CTR-053-003c

See response to CTR-002-006.

Comment ID: CTR-058-012
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: 2,3,7,8-TCDD ("dioxin"). EPA has proposed a criterion for 2,3,7,8-TCDD ("dioxin') and is encouraging the state to implement the TEQ approach in implementing this criterion. WSPA does not agree with the TEQ approach entirely and strongly urges EPA and the state to wait until EPA and EPA's Science Advisory Board complete the re-evaluation of the health risk assessment of dioxin and its congeners. EPA may find that some congeners, especially the more highly substituted congeners which seem to be ubiquitous in the environment, are not as toxic as originally perceived. Until EPA's studies are complete, EPA and the state should regulate 2,3,7,8-TCDD based on the criteria set by EPA for this compound in the proposed rule.

Response to: CTR-058-012

See response to CTR-002-006.

Comment ID: CTR-095-003
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Dioxin is only regulated in one compound. Ca. used to have standards for all 17 dioxin compounds. The proposed new standard for only one Dioxin compounded is .014 parts per billion. It should be at least .0014 ppb; OR BETTER: ZERO!

Response to: CTR-095-003

See response to CTR-002-006.

Comment ID: CTR-097-003
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: In addition the proposed standards apply to only one dioxin compound, and that proposed standard is O.014 parts per billion. A more appropriate standard for dioxin - ALL dioxin compounds- is zero parts per billion.

Response to: CTR-097-003

See response to CTR-002-006.

Comment ID: CTR-104-004a
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA

Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-104-004a

See response to CTR-002-006.

Comment ID: CTR-106-004a
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: Increasing the limits on toxins means that we postpone the goals of the Clean Water Act to make U.S. water "fishable and swimmable". Any progress made will not be expanded toward making our waters cleaner and mediocre programs will be introduced which do not improve the condition of our state's water quality. More protective standards must be created which will consider all 17 toxic pollutants of concern.

Response to: CTR-106-004a

See response to CTR-002-006.

Comment ID: CTR-109-003
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-09a Dioxin Human Health
References:

Attachments? N
CROSS REFERENCES

Comment: Third, California used to have standards for all 17 dioxin compounds. The proposed new standard applies only to one, and that proposed standard is severely inadequate.

Response to: CTR-109-003

See response to CTR-002-006.

Comment ID: CTR-110-002
Comment Author: Judith A. Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/02/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: Please consider standards for all seventeen dioxin compounds, not just one.

Response to: CTR-110-002

See response to CTR-002-006.

Comment ID: CTRH-001-012
Comment Author: Greg Karras
Document Type: Public Hearing
State of Origin: CA
Represented Org: Comm. for Better Environ.
Document Date: 09/17/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: On dioxin, despite proof that there are 17 dioxin compounds which harm the fishing public, EPA proposes a standard for only one of these compounds. EPA then says that it encourages the state to use the states previous scientifically correct standards for all 17 dioxins, instead of using the one EPA proposes, which deregulates 16 of the 17 most toxic chemicals known to science.

Our question here is, why does EPA think the state will have the courage to do the right thing about dioxin if EPA doesn't?

Response to: CTRH-001-012

See response to CTR-002-006.

Comment ID: CTRH-001-051
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-09a Dioxin Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: The toxicity equivalents notion is sort of held up as a good idea, and all states should go about doing that. It seems to me a simple step to say that the state has to do it. Just make those other 16 congeners --

And, of course, Baykeeper has signed on and there are a number of groups in the Bay Area that have signed on to the statewide notion of a zero dioxin standard anywhere possible. And I think that would be certainly the most practical place to put a zero discharge standard, would be in the standards themselves.

And to the extent there's other issues related to the particular permits, then we would obviously raise those at the time the permits came up. So we would propose a zero number for dioxin and all the congeners at this point.

Response to: CTRH-001-051

See response to CTR-002-006.

Subject Matter Code: C-10b PCBs Aquatic Life

Comment ID: CTR-037-010
Comment Author: Hampton Roads Sanitation Dist.
Document Type: Sewer Authority
State of Origin: VA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-10b PCBs Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: 10. EPA has modified the PCB criteria from an approach where each aroclor has its own criteria to one where a single criterion applies to the sum of all aroclors. However, the new criterion does not represent the sum of the criteria for the aroclors. This, in effect, results in a much more stringent PCB criterion because an effluent previously could discharge several aroclors at concentrations which were not detrimental to biota but now those same concentrations add up to a sum which is greater than the new criterion. The 1995 Update document does not address why this change is made, and justification could not be located in the proposed rule. Such changes must be technically and scientifically defensible and necessary to protect and support designated uses. EPA should provide data and logic supporting the new approach and illustrate why it is now necessary to protect aquatic organisms.

Response to: CTR-037-010

The Agency agrees that the presentation of the aquatic life criteria for polychlorinated biphenyls (PCB) in the criteria matrix for this proposal differ from that in the NTR as amended; for this final rule, aquatic life criteria are expressed as the sum of aroclors (1242, 1254, 1221, 1232, 1248, 1260 and 1016, CAS numbers 53469219, 11097691, 11104282, 11141165, 12672296, 11096825 and 12674112, respectively) while for the NTR, as amended, the criteria limits are expressed for each of seven different aroclors. The Agency agrees that a criterion based on the sum of several aroclors may be more stringent than a criterion where each of several individual aroclors has a concentration limit. For example, a criterion of 0.014 ug/L applying to the sum of seven aroclors is more stringent than each of seven aroclors having a concentration limit of 0.014 ug/L.

The Agency does not agree that justification for a criterion based on the sum of aroclors could not be located in the proposed rule. Page 42168 of the Preamble states: "The presentation of the polychlorinated biphenyls (PCB) criteria in the criteria matrix for this proposal differ from that in the NTR, as amended: for this proposal, the criteria are expressed as a total of all aroclors, while for the NTR, as amended, the criteria are expressed for each aroclor." The aquatic life criteria proposed in the CTR were based on the criteria contained in the 1980 criteria document entitled, Ambient Water Quality Criteria for Polychlorinated Biphenyls, (EPA 440/5-80-068, October 1980) which was included in the Record for the proposed rule. This criteria document explains the derivation of aquatic life criteria based on total PCBs. Therefore, a criteria based on the sum of aroclors is comparable with the aquatic life criteria presented in the 1980 criteria document.

Subject Matter Code: C-11b PAHs Aquatic Life

Comment ID: CTR-060-014
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-11b PAHs Aquatic Life
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

PAHs criteria

EPA's proposed criteria for high molecular weight (HMW) carcinogenic PAHs (e.g., Benzo (a) Anthracene, Benzo (a) Pyrene, Benzo (b) Fluoranthene, Benzo (k) Fluoranthene, Chrysene, Dibenzo (a,h) Anthracene, Indeno (1,2,3-cd) Pyrene) used a number of assumptions which have made the resulting criteria overly conservative. Following is a discussion of these factors.

* PAHs are highly hydrophobic molecules and consequently bind to available suspended organic matter. Currently accepted methods for measuring concentrations of PAHs in water neglect the binding of such hydrophobic compounds to suspended organic matter(*1). The dissolved fraction (DOM) of this suspended material passes through a 0.45um filter and the organic extraction required for analysis of PAHs insures that both DOM-bound and free PAH will be reported. Since only the free PAH is bioavailable, this results in the proposed criteria being unnecessarily overprotective. The PAH criteria should account for the bio-availability of PAHs, as they do for the bio-availability of metals (e.g., dissolved criteria vs. total recoverable, translators, WERs).

* The simple use of octanol-water partition coefficients or fugacity modeling show that these HMW PAHs are only vanishingly soluble in seawater and to reach the proposed criteria values would have to originate from a large well-mixed source. For instance, assuming the HMW PAHs has a log octanol/carbon partition coefficient (log Koc) of 5.0, the sediment source would have to be 4.9 ppm in order to be the source for the proposed water quality criterion of 0.049 ppb. While there may be sites where this level has been reported for total PAHs, the highest values for a single HMW PAH reported at a very contaminated site was 2.3 ppb of benzo(a)pyrene(*2). Since the source of HMW PAHs in fish is unlikely to be the water column, the back-calculation of human health standards to water standards makes little sense.

* The fish consumption rate of 6.5 g/day used is not representative of fish consumption within the State of California, and overestimates exposure. This value is reported by the EPA to represent an estimate of average consumption of fish and shellfish from estuarine and fresh waters by the U.S. population(*3) . The draft EPA Exposure Factors Handbook (*4)(EFH) summarizes studies on the intake of fish and shellfish, and includes study results for Northern and Southern California from the National Marine Fisheries Service. While this data is compiled for fish from marine habitats, other data summarized in

Table 10-8 of the draft EFH suggests that the percentage of the population consuming and the mean daily fish intakes are higher for fish from marine habitats than for freshwater/estuarine habitats. The mean daily intake of marine finfish for anglers was 2.0 g/day for both Northern and Southern California, and the intake was 0.2 or 0.3 g/day on a per capita basis in the coastal population. The value of 2.0 g/day would be a more reasonable consumption rate and should be sufficiently health-protective of the more highly exposed sub-population of the state, because this intake is restricted to the angler population, which may reasonably be expected to consume their own catch and to represent a greater exposed population than the entire population of the state. The intake rate from this database is more up-to-date and is geographically representative. The criteria should be recalculated using the California fish intake rate.

* The use of a single, deterministic value of the BCF for each chemical is a gross oversimplification, and is likely to overestimate exposure. Some of the issues that should be considered in the selection of BCF values to use in the analysis are listed below:

* Most BCFs are reported for whole body samples, whereas the edible portion of the fish is typically only a fillet (muscle, skin, and adipose tissue). For example, in a study of the uptake and distribution benzo(a)pyrene in Northern Pike, less than 3% of the total accumulation of benzo(a)pyrene was located in the edible portion of the fish. The use of whole body BCFs in general overestimates the concentration of the chemical in the edible portion of the fish.(*5)

* BCFs have been shown to vary widely depending upon the fish species. Fish species with a higher content of lipids tend to bioconcentrate lipophilic substances to a greater degree than less oily, leaner fish from the same environment. In addition, fish species which lack or have a reduced capacity for metabolic elimination of a chemical tend to bioconcentrate chemicals to a greater degree. For example, the BCF for benzo(a)pyrene in snails is 82,000, while the BCF for benzo(a)pyrene in bluegill is 2,600.(*6) Creel studies should be utilized to select fish species caught and consumed by recreational fishers in California, and the appropriate BCFs selected to represent the regional fish populations ingested.

* Because of their low solubility and high affinity for organic carbon, PAHs in aquatic systems are primarily found sorbed to particles that are either settled to the bottom or are suspended in the water column.(*7) The sediments can be major sinks for PAHS. The concept of estimating concentrations in fish from water concentrations and BCF factors neglects the potentially very significant contribution of uptake from sediments into benthic organisms and subsequent ingestion by higher trophic levels.

* The presence of particulate organic material (POM) and dissolved organic material (DOM) may exhibit a significant effect on the BCF measured. For example, the BCF for benzo(a)pyrene in bluegills decreases from 2,600 to 220 in the presence of 20 mg/L DOM.(*8) Because the amount of organic materials in the waterbody may vary depending upon the freshwater or estuarine habitat, the BCFs should reflect the organic material in the freshwater and estuarine water bodies in California.

* Several studies by NOAA and others have shown that HMW PAHs do not bioaccumulate in fish tissue even under very polluted environmental conditions.(*9) This is because they either pass through the gut unchanged,(*10) or are extensively metabolized(*11) and excreted.(*12) Metabolism occurs in several tissues, but primarily in the liver and gut. Metabolism that occurs in the gut reduces the amount of PAH that is available for distribution within the fish flesh.

* There is a wide range of published BCFs for HMW PAHs. This is because a number of different methods and assumptions were used to deduce these values. Most laboratory studies derived BCFs

during short-term exposures to environmentally irrelevant high concentrations of PAHs, while field studies assumed that the only source of PAHs was the water column. In short-term high level exposures, the fish does not reach equilibrium and metabolic capacities are overwhelmed. The inability of fish to clear these PAHs results in apparently high BCFS. However, as discussed above, high levels of HMW PAHs do not occur even at very polluted sites.

* The use of BAF values in future evaluations is suggested in the proposed Water Quality Standards document. With regard to carcinogenic PAHs, extensive metabolism of the compounds by high-trophic-level consumers such as predatory fish has been demonstrated, therefore food chain biomagnification of these compounds does not appear to be significant, and the use of a BAF does not result in the conservatism that a BCF does.

* The EPA uses the oral slope factor for benzo(a)pyrene as the toxicity criteria for the other carcinogenic PAHs. While it is our understanding that the EPA does not have a national standard for assigning cancer potencies to different PAHs, both the EPA Region IX(*13) and the California EPA(*14) have policies which result in the assignment of toxicity equivalence factors to the carcinogenic PAHs. In general, the other carcinogenic PAHs are less potent than benzo(a)pyrene (i.e. the toxicity equivalence factors are less than one). Because the proposed Water Quality Standards are specific to California, the toxicity criteria used in the derivation should at a minimum reflect either current California EPA or EPA Region IX policies.

* The EPA should consider the use of probabilistic approaches to determine numeric water quality standards related to fish ingestion. The wide variability and relatively high uncertainty in the essential exposure parameters related to the intake rates, species of fish consumed, bioconcentration factors, and human sub-populations are ideally suited to a non-deterministic approach, and the expansion of studies which report distributional data should make a probabilistic approach feasible.

(*1) Readman, J.W., et al. 1982. Aquatic distribution and heterotrothic degradation of polycyclic aromatic hydrocarbons (PAH) in the Tamar Estuary. Estuar. Coast. Shelf Sci. 14: 369-389.

(*2) Krahn, M..M. et al. 1986. Associations between metabolites of aromatic compounds in bile and the occurrence of hepatic lesions in English sole (Parophys vetulus) from Puget Sound, Washington. Arch. Env. Contam. Toxicol. 15: 6167.

(*3) U.S. EPA, 1989. Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish. Office of Water Regulations and Standards. EPA-503/8-89-002.

(*4) U.S. EPA, 1996. Exposure Factors Handbook. EPA/600/P-95/002Ba. Office of Research and Development.

(*5) Balk, L.; Meijer, J.; DePierre, J.W.; Appelgren, L.E. 1984. Toxicology and Applied Pharmacology, 74, 430-449.

(*6) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*7) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*8) ATSDR, 1997. Agency for Toxic Substances Disease Registry. Toxicological Profiles on CD-ROM. Lewis Publishers, Boca Raton, Florida.

(*9) Krahn, M.M. et al. 1986. Associations between metabolites of aromatic compounds in bile and the occurrence of hepatic lesions in English sole (Parophys vetulus) from Puget Sound, Washington. Arch. Env. Contam. Toxicol. 15: 6167.

(*10) Niimi, A.J. and G.P Doorkhran. 1989. Dietary absorption efficiencies and elimination rates of polycyclic aromatic hydrocarbons (PAHS) in rainbow trout (Salmo gairdneri). Env. Toxicol. Chem. 8: 719-722.

(*11) VanVeld,P.A.etal. 1988. Induction of monooxygenase activity in the intestine of spot (Leiostomusxanthurus), a marine teleost, by dietary aromatic hydrocarbons. Drug Metab. Disposition l6: 659-65; and Stegeman, J.J. 1978.

(*12) Krahn, M.M. et al. 1992. Mass spectrometric analysis for aromatic compounds in bile of fish sampled after the Exxon Valdez oil spill. Env. Sci. Technol. 26: 116-126.

(*13) U.S. EPA Region IX, 1993. Memo from Gerald Hiatt, Senior Risk Assessment Advisor at USEPA Region IX, to Richard Becker, Chief of Human and Ecological Risk at California EPA. Subject: EPA national and regional policies on assessment of cancer risks from exposure to mixtures of PAHs. May 25, 1993.

(*14) Califomia EPA, 1994. California Environmental Protection Agency Criteha for Carcinogens. November 1, 1994.

Response to: CTR-060-014

1. In response to the comment that EPA's proposed criteria for PAHs are overly conservative because they are not based on the freely dissolved fraction in water, EPA disagrees. While EPA agrees that the freely dissolved fraction of PAHs is the most bioavailable fraction for uptake by aquatic organisms, EPA believes that it would be premature to place in the final rule a criterion that is based on bioaccumulation factors normalized to the freely dissolved fraction because EPA has not yet completed peer review of its proposed national methodology for taking this approach. Until EPA completes the peer review of its national methodology for development of bioaccumulation factors, EPA believes it is most appropriate to base the criterion on the BCF, as is consistent with the NTR and EPA's current national recommended section 304(a) criteria. With respect to PAHs, EPA disagrees that its BCF of 30 necessarily results in an overly conservative criterion. Specifically, this BCF was derived from a study by Lu et al. (1977) and was measured in a model aquatic ecosystem environment containing multiple species at different trophic levels (e.g., algae, zooplankton, mosquito larvae, fish). Therefore, it is likely that some organic carbon was present in the study and that some sorption of the PAH compound (benzo-alpha-pyrene) onto dissolved and particulate carbon occurred thereby reducing the bioavailability of some portion of the PAH compound present. Further, since sufficient information is not presented in the Lu et al. study to estimate the freely dissolved fraction of the PAH compound, there is no basis for assuming that the bioavailability in the Lu et al. study was greater than waters in California generally.

EPA acknowledges that its revised national human health methodology would seek to develop water quality criteria for PAHs that are based on BAFs that consider the freely dissolved fraction in water (see 63 Fed. Reg. 43,756-43828; August 14, 1998, specifically pp. 43806-43823). However, this methodology has not been finalized and is currently undergoing external scientific peer review. EPA believes that

scientific peer review is essential to maintaining the scientific defensibility of its water quality criteria. In the aforementioned notice, EPA described its proposed methodology for appropriately determining bioaccumulation factors that are used to derive a criterion. As proposed, this would entail a two-step process: (1) calculation of a baseline BAF for organisms at each relevant trophic level from available field, laboratory, or model-derived bioaccumulation data, and (2) conversion of the trophic level-specific baseline BAFs to AWQC BAFs that reflect factors affecting bioavailability at the sites to which the AWQC is being applied. These factors include lipid content of consumed aquatic organisms and the organic carbon content (i.e., dissolved and particulate organic carbon) of waters applicable to the AWQC. In addition, EPA's proposed methodology includes guidance on selection of octanol-water partition coefficients (Kow), which are integral to several aspects of the methodology.

Although strong similarities exist between EPA's proposed national human health methodology (which includes the bioaccumulation methodology) and the 1995 methodology established under the Great Lakes Water Quality Initiative, all of the elements of EPA's proposed national bioaccumulation methodology require scientific peer review since it would be applied in a much broader scope than the GLWQI methodology (i.e., the national methodology applies to estuaries, lakes, streams, rivers throughout the United States whereas the GLWQI methodology applies just to waters of the Great Lakes region). In addition, the proposed national bioaccumulation methodology contains substantive changes since the 1995 publication of the GLWQI methodology (e.g., new guidance on selecting Kow values, revised estimates of food chain multipliers, additional guidance for the use of field data, revised default assumptions on lipid content of consumed aquatic organisms and particulate and dissolved organic carbon).

At the time of this rulemaking, EPA did not have sufficient time to adapt the GLWQI methodology in order to develop National or California-specific BAF estimates for the 304(a) criteria being promulgated, and also have these modifications peer reviewed. After the peer review process on the revised national methodology is complete, EPA plans to update its National 304(a) criteria on a periodic basis. As National 304(a) criteria are updated, EPA will evaluate the need to promulgate revisions to criteria in the CTR. Given that California is the only state with no numeric human health criterion in place for PAHs, and given that EPA has not completed a national methodology for developing BAFs on a freely dissolved basis, EPA believes it is most appropriate to promulgate the PAH criterion using the BCF that is consistent with the NTR and its most current national 304(a) recommendations.

2. In response to the comment that back calculation of human health criteria makes little sense because the source of PAHs in fish is not likely to be the water column, EPA disagrees that expressing human health criteria in the form of ambient water column concentrations is inappropriate for hydrophobic chemicals such as PAHs. For highly hydrophobic chemicals (i.e., log Kow > 6), EPA agrees that it is often the case that the concentrations in the water column are much lower than those in other environmental compartments such as sediment or food. EPA also acknowledges that the contribution of chemicals in food and sediment-based organisms to overall chemical uptake in higher trophic level organisms such as fish can be substantial, compared to the water column. However, EPA believes that expressing human health criteria in terms of concentrations in the water column concentrations is valid because environmental compartments in aquatic ecosystems (water, organisms, sediments) are all interconnected and therefore, concentrations of contaminants within these compartments are continuously being exchanged as a result of ongoing and competing chemical and biological partitioning processes. At equilibrium, contaminant concentrations within these environmental compartments are expected to be closely correlated, which is consistent with chemical equilibrium partitioning theory (i.e., higher water column concentrations would be correlated with higher sediment and prey concentrations). Thus, valid expressions of human health criteria can in theory be made for various environmental compartments (water, organisms, sediments). The Agency's choice of the water column for expressing

human health criteria largely reflects the need to use chemical criteria for determining acceptable chemical loadings to the water column and because more advanced implementation procedures are available for relating water column concentrations to chemical loadings, as compared to other compartments such as sediments and fish tissue.

3. In response to the comment concerning fish consumption, EPA disagrees with the comment regarding the consumption rate. For additional discussion of this issue, refer to the response to CTR-002-002a concerning fish consumption.

4. EPA disagrees with the comment that because lipid content in finfish is generally higher on a whole body basis compared to edible portions (e.g., fillet), the use of whole-body BCFs to calculate EPA's ambient water quality criteria significantly overestimates the concentration of the chemical in the edible portion of the fish and by implication is overly conservative. EPA disagrees with this comment because for lipophilic compounds such as PAHs, each BCF used in calculation of a human health ambient water quality criterion is first normalized to the lipid content of the tissue in which the residue was measured (45 FR 79346-79348). For example, BCFs determined from whole body residues are adjusted for the lipid content measured in the whole body, and BCFs determined from fish fillet residues are adjusted for the lipid content measured in the fish fillet. EPA performs this lipid normalization because it is widely recognized that accumulation of lipophilic chemicals is generally proportional to lipid content (Mackay 1982; Connolly and Pederson, 1988; Thomann, 1989) and this adjustment makes BCFs determined for different tissues and species comparable. Because of this proportionality with lipid content, steady-state BCFs for lipophilic compounds can be extrapolated from one tissue to another so long as they are expressed on a percent lipid basis. Once the average of the individual lipid normalized, BCFs are determined, this average, lipid normalized BCF is then adjusted to reflect the lipid content in the edible portions of aquatic organisms consumed by humans, which is 3.0% based on the EPA's 1980 Human Health Water Quality Criteria Methodology (45 FR 79318). In this way, the final BCF used to determine the human health water quality criterion reflects the chemical accumulation expected in the edible portions of consumed aquatic organisms. EPA further notes that for non-lipophilic compounds such as metals where lipid normalization does not apply, BCFs determined from only the edible portions are used in criteria calculations, per EPA's 1980 methodology.

References:

Connolly, J. and C. Pedersen. 1988. A Thermodynamic-based Evaluation of Organic Chemical Accumulation in Aquatic Organisms. Environ. Sci. Technol. 22: 99-103.

Mackay, D. 1982. Correlation of Bioconcentration Factors. Environ. Sci. Technol. 16: 274-278.

Thomann, R.V. 1989. Bioaccumulation Model of Organic Chemical Distribution in Aquatic Food Chains. Environ. Sci. Technol. 23: 699-707.

5. In response to the comment that EPA's BCFs for PAHs are oversimplified and overly conservative because BCFs have been shown to vary widely depending on fish species and therefore, BCFs should only be used from organisms consumed by recreational fishers in California, EPA disagrees. EPA agrees that BCFs from specific organisms caught and consumed in California, if available and appropriately weighted by consumption data, would allow for derivation of BCFs that would be most tailored to the California situation. However, EPA believes that the use of BCFs in its 304(a) criteria are still appropriate to California because they were selected and derived to reflect accumulation in aquatic organisms consumed throughout the United States, including those consumed in California. While EPA agrees that BCFs can vary depending on the species due to a variety of factors (e.g., lipid content of the

organism, differences in chemical metabolism, bioavailability differences, duration of exposure), EPA has taken a number of steps in its determination of BCFs for its 304(a) criteria to limit this variability. For example, EPA in its 1980 criteria guidance recommends that individual BCFs be adjusted for lipid content and be based on steady-state conditions (typically > 28 days) in order to reduce variability in BCF estimates. Furthermore, in its calculation of human health criteria, the final BCF used is adjusted for the consumption-weighted lipid content based on the variety of aquatic organisms consumed throughout the United States. In its more recent Great Lakes Water Quality Initiative guidance (60 FR 15366) and in its proposed national human health criteria guidance (63 FR 43,756), EPA also recommends BAFs and BCFs also be adjusted based on the freely dissolved fraction of the contaminant in water and be determined separately for organisms of different trophic levels as further means for reducing variability. However, until EPA's national methodology for deriving human health water quality has undergone scientific peer review and is made final, the human health criteria for PAHs in the final CTR represent the most recent 304(a) criteria available and are based on the most current national human health criteria methodology. With respect to BCFs for PAHs, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977) which was measured from a 33-day exposure in a model aquatic ecosystem environment. EPA believes that this value is appropriate because it is believed to more closely approximate steady-state conditions compared to other, more variable BCF values which were based on much shorter exposure periods (e.g., 3-days) and because it accounts for the effects of metabolism which is known to be important for PAHs.

6. In response to the comment that the BCF neglects potential uptake from sediments for PAHs into benthic organisms and subsequent ingestion by higher organisms, EPA agrees that in general, standard laboratory-based BCFs involving water-only exposures ignore the potential uptake of contaminants from sediment-dwelling organisms (and other prey species). For some chemicals (e.g., high log Kow chemicals that are not readily metabolized), omission of exposure via the aquatic food web can underestimate exposure and bioaccumulation. For this and other reasons, EPA relies on bioaccumulation factors (BAFs), which incorporate multiple routes of exposure, for determining human health water quality criteria under the Great Lakes Water Quality Initiative Guidance (60 FR 15366). EPA is also in the process of adopting this general BAF approach in its proposed revisions to its 1980 National guidance for determining human health water quality criteria (63 FR 43,756). However, because the Great Lakes BAFs rely on a number of considerations and assumptions that are specific to the Great Lakes (i.e., lipid content of aquatic species consumed in the Great Lakes region, freely dissolved fraction in the Great Lakes, food chain multipliers specific to the Great Lakes ecosystem), they cannot be directly applied to national 304(a) criteria or other areas without adjustment and significant additional analyses to develop appropriate BAFs. As stated earlier, EPA is in the process of updating its national methodology which is undergoing scientific peer review and is developing national, default BAFs. Until such time as EPA revises its national methodology, the human health criteria for PAHs in the CTR represent the most recent 304(a) criteria available and are based on the most current national methodology.

With respect to EPA's PAH criteria, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977). This BCF was measured from a 33-day exposure period in a model aquatic ecosystem environment using a model food chain that included benthic organisms. Therefore, while the model ecosystem used by Lu et al (1977) may not completely replicate the exposure conditions of typical field situations, EPA believes that it does not ignore potential exposure via benthic organisms and disagrees with the comment.

7. In response to the comment that DOM (dissolved organic matter) may exhibit a significant effect on the BCF for PAHs, EPA agrees with the commenter that DOM (what EPA calls dissolved organic carbon or DOC) can influence the freely dissolved fraction of PAHs and other nonpolar organic chemicals. As stated above, EPA agrees that the freely dissolved fraction of PAHs is the most bioavailable fraction for

uptake by aquatic organisms. However, EPA believes that it would be premature to place in the final rule a criterion that is based on bioaccumulation factors normalized to the freely dissolved fraction in water because EPA has not yet completed peer review of its proposed national methodology for taking this approach. Until EPA completes the peer review of its national methodology for development of bioaccumulation factors, EPA believes it is most appropriate to base the criterion on the BCF, as is consistent with the NTR and EPA's current national recommended section 304(a) criteria.

Although EPA based its bioaccumulation factors (BAFs) on the freely dissolved fraction for the Great Lakes Water Quality Initiative (GLWQI) rulemaking, EPA did not have sufficient time to adapt the GLWQI methodology in order to develop National or California-specific BAF estimates for the human health criteria being promulgated, and also have these modifications peer reviewed. After the peer review process on the revised national methodology is complete, EPA plans to update its National 304(a) criteria on a periodic basis. As National 304(a) criteria are updated, EPA will evaluate the need to promulgate revisions to the CTR. Thus, given that California is the only state with no numeric human health criterion in place for PAHs, and given that EPA has not completed a national methodology for developing BAFs on a freely dissolved basis, EPA believes it is most appropriate to promulgate the PAH criterion using the BCF that is consistent with the NTR and its most current national 304(a) recommendations.

With respect to the BCF used to derive the PAH criteria, EPA's BCF was derived from a study by Lu et al. (1977) which was measured in a model aquatic ecosystem environment containing multiple species at different trophic levels (e.g., algae, zooplankton, mosquito larvae, fish). Therefore, it is likely that some organic carbon was present in the study and that some sorption of the PAH compound (benzo-alpha-pyrene) onto dissolved and particulate carbon occurred thereby reducing the bioavailability of some portion of the PAH compound present. Further, since sufficient information is not presented in the Lu et al. study to estimate the freely dissolved fraction of the PAH compound, EPA cannot determine the extent to which the freely dissolved fraction associated with the Lu et al. (1977) study would be systematically higher or lower than sites in California to which the criteria would apply.

8. In response to the comment EPA's PAH criteria are overly simplified and overestimates exposure because metabolism of PAHs and other factors indicate that some PAHs do not bioaccumulate extensively in fish, EPA disagrees. EPA agrees that some PAHs are known to metabolize rapidly in fish which results in much lower residues than would be predicted by the octanol-water coefficient (Kow). For this very reason, EPA chose not to rely on Kow-based estimates of bioconcentration for deriving the proposed human health water quality criteria for PAHs. Instead, EPA based the proposed criterion for PAHs on a bioconcentration factor of 30 determined for mosquito fish from Lu et al. (1977). This BCF was measured from a 33-day exposure in a model aquatic ecosystem environment and incorporates the effects of metabolism by organisms at various trophic levels. Thus, EPA believes that its BCF is appropriate for PAHs and is not overly conservative because it takes into account the effects of metabolism.

9. Another comment was made that EPA's BCF for PAH is oversimplified and overestimates exposure because: (1) a wide range of BCFs exists for high molecular weight PAHs, (2) different methods are used to determine BCFs, (3) BCFs are used from exposure durations that are too short, (4) use of field BCF studies only assumes that water is the exposure source, (5) BCF studies involve high exposure concentrations. While EPA agrees that BCFs can vary depending on the species due to a variety of factors (e.g., lipid content of organism, differences in chemical metabolism, bioavailability differences, duration of exposure), EPA has taken a number of steps in its determination of BCFs for its 304(a) criteria to limit this variability and disagrees with this comment. For example, EPA in its 1980 criteria guidance recommends that individual BCFs be adjusted for lipid content and be based on steady-state

conditions (typically > 28 days) in order to reduce variability in BCF estimates. Furthermore, in its calculation of human health criteria, the final BCF used is adjusted for the consumption-weighted lipid content based on the variety of aquatic organisms consumed throughout the United States. EPA also recommends that exposure concentrations be below levels that are cause overt toxicity to the test organisms. In its more recent Great Lakes Water Quality Initiative guidance (60 FR 15366) and in its proposed national human health criteria guidance (63 FR 43,756), EPA also recommends BCFs and bioaccumulation factors (BAFs) also be adjusted based on the freely dissolved fraction of the contaminant in water and be determined separately for organisms of different trophic levels as further means for reducing variability. However, until EPA's national methodology for deriving human health water quality has undergone scientific peer review and is made final, the human health criteria for PAHs in the CTR represent the most recent 304(a) criteria available and are based on the most current national human health criteria methodology. Therefore, EPA believes BCFs derived using its existing 1980 national methodology and BAFs resulting from its forthcoming revised national methodology are not oversimplified and do not result in overly conservative estimates of chemical accumulation.

With respect to BCFs for PAHs, EPA used a bioconcentration factor of 30 for mosquito fish from Lu et al. (1977) which was measured from a 33-day exposure period in a model aquatic ecosystem environment. This value was chosen for the BCF because it is believed to more closely approximate steady-state conditions compared to other, more variable BCF values which were based on much shorter exposure periods (e.g., 3-days) and accounts for the effects of metabolism which is known to be important for PAHs. Therefore, EPA disagrees that this BCF is oversimplified or results in an overestimation of PAH accumulation.

EPA disagrees that BCFs based on field data are inappropriate because they assume that chemical exposure result from only from water. On the contrary, such field-measured BCFs (now called BAFs) reflect uptake from multiple exposure routes (water, diet, sediment) but merely reference the accumulation to the water concentration. EPA believes that expressing human health criteria in terms of concentrations in the water column concentrations is valid because environmental compartments in aquatic ecosystems (water, organisms, sediments) are all interconnected and therefore, concentrations of contaminants within these compartments are continuously being exchanged as a result of ongoing and competing chemical and biological partitioning processes. At equilibrium, contaminant concentrations within these environmental compartments are expected to be closely correlated, which is consistent with chemical equilibrium partitioning theory (i.e., higher water column concentrations would be correlated with higher sediment and prey concentrations). Thus, valid expressions of human health criteria can in theory be made for various environmental compartments (water, organisms, sediments). The Agency's choice of the water column for expressing human health criteria largely reflects the need to use chemical criteria for determining acceptable chemical loadings to the water column and because more advanced implementation procedures are available for relating water column concentrations to chemical loadings, as compared to other compartments such as sediments and fish tissue.

10. Regarding the comment that BAFs should be used for further bioaccumulation evaluations in water quality criteria documents with particular reference to PAHs, EPA agrees. As discussed previously, EPA is in the process of revising its national human health methodology and has proposed a methodology that would develop water quality criteria for PAHs that are based on BAFs (see 63 Fed. Reg. 43,756-43828; August 14, 1998, specifically pp. 43806-43823). However, this methodology has not been finalized and is currently undergoing external scientific peer review. EPA believes that scientific peer review is essential to maintaining the scientific defensibility of its water quality criteria. When this methodology is made final, EPA will develop revised 304(a) criteria for chemicals, including PAHs, that are based on BAFs rather than BCFs. EPA notes that with respect to the BCF used in deriving the proposed PAH criteria, this BCF was similar to a BAF because it was measured in a model aquatic ecosystem

environment that contained organisms at different trophic levels.

11. The proposed PAH water quality standards for California are part of a Clean Water Act (CWA) Section 303promulgation that EPA has undertaken. For this promulgation, EPA utilizes published IRIS cancer slope factors and utilizes published guidance documents and adopted Agency policies. As such, the commenter is correct that EPA does not have an established policy on assigning cancer potencies based on TEFs to the various PAH chemicals. However, the State of California can endeavor to establish subsequent standards based on their own current policy. EPA would most likely approve such a decision during the Agency's triennial review of State standards, as long as the standard was scientifically defensible and was consistent with CWA requirements.

12. EPA agrees with the commenter that probabilistic approaches can be a viable option for addressing uncertainty and variability in the development of ambient human health water quality criteria, provided sufficient data are available from which to estimate statistical properties of input distributions (e.g., mean, standard deviation, type of distribution) and the methods are scientifically defensible. However, in many situations, insufficient data are available to estimate the necessary statistical properties of input distributions with sufficient confidence to provide meaningful results. Furthermore, it is highly unlikely that scientifically defensible input distributions could be used for all input parameters for all criteria in the CTR. It should be noted that EPA's criteria methodology does not preclude States and Tribes from using probabilistic approaches for criteria determinations, provided such approaches produce criteria which are scientifically defensible and achieve an appropriate level of protection. However, EPA does not consider the use of probabilistic modeling approach to be a prerequisite for deriving scientifically defensible criteria. EPA has demonstrated and continues to believe that scientifically defensible water quality criteria can be produced based on point estimates of toxicity and exposure parameters provided the estimates are based on reasonable and appropriate assumptions (i.e., worst case assumptions for all input parameters would probably not be reasonable because they would probably correspond to a highly unlikely or nonexistent risk scenario). EPA's criteria are not based on worst case assumptions but rather are based on assumptions that reflect different levels of conservatism depending on the input parameter. Together, these input parameters result in criteria that the Agency believes achieves an appropriate level of protection for its national 304(a) criteria and are appropriate for promulgation in California.

Subject Matter Code: C-12a THMs Human Health

Comment ID: CTR-020-018
Comment Author: City of Stockton
Document Type: Local Government
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Subject Matter Code: C-12a THMs Human Health
References:
Attachments? Y
CROSS REFERENCES

Comment: II. Use of New Scientific Information

The City acknowledges and supports EPA's update of several water quality criteria including those for mercury, cadmium and arsenic. While a number of criteria were updated to reflect current scientific information, there are a few notable exceptions.

The following briefly addresses the key updates and omissions that should be addressed in the final publication of this rule.

7. Adoption of More Stringent Requirements for Maximum Containment Levels ("MCLs") is Inappropriate

A number of the water quality-based criteria establish water ingestion-related requirements more stringent than tap water criteria. This leads to the anomalous result that ingestion of effluent is regulated more stringently than ingestion of tap water. An example of this problem is bromodichloromethane ("BDCM") and dibromochloromethane ("DBCM") which are two types of halomethanes formed by chlorination of effluents. EPA studies recognize that tap water contains higher levels of these constituents, but their presence is tolerated due to the beneficial effects of chlorine on killing bacteria. The CTR would regulate these pollutants in surface waters at one-tenth the level present in tap water.

EPA policies recognize that this is not a reasonable result and that application of the MCL should be considered protective in such instances (see, 62 Fed. Reg. 27709). Consistent with recent EPA action to delete the arsenic criteria from the CTR the Agency should delete the water ingestion-related requirements for BDCM and DBCM. Such action is even more appropriate for these pollutants as they are volatile and very shortlived in the environment. Thus, the discharge of these pollutants by publicly owned treatment works presents no actual threat of drinking water contamination.

Response to: CTR-020-018

EPA disagrees with commenter. EPA believes that discharges can meet both the requirements of the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA) after the CTR is promulgated. EPA believes that any final limits for THMs would be feasible to meet because it is unlikely that a discharger would receive criteria end-of-pipe limits due to the dilution in the receiving stream, as well as other factors taken into account, when translating a criterion into a water quality criteria-based effluent limit. EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and

CTR-025-003a). Under the CWA, water quality criteria are required to protect the designated use, without respect to economic factors. Under the SDWA, EPA may take into account cost or availability of treatment technology in setting an MCL. As expressed by the commenter, the presence of the two trihalomethanes mentioned is a matter of balancing the potential for chemical risk associated with the formation of these chlorine byproducts and the beneficial effects of chlorine reducing microbial risk. Although EPA has stated that MCLs may be considered protective in the absence of water quality criteria, the Agency recommends the development of water quality criteria since the methodology specifically accounts for fish ingestion route exposure. Because water quality criteria take into account exposure to fish as well as water, they may be more stringent. Other factors that may also account for stringency differences are discussed in the response to CTR-025-002a. Concerning volatility, EPA does not disregard chemicals simply because they are volatile. Many chemicals may be somewhat volatile or short-lived, but may present health risks due to the frequency of discharge, biomagnification, or other factors.

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Subject Matter Code: C-12a THMs Human Health
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C-16

Comment: Human health water quality criteria for a number of other priority pollutants are at levels significantly below the corresponding California SDWA MCL. While Metropolitan favors a margin of safety between human health-water quality criteria and the SDWA MCL, significant differences between these two regulatory requirements can create problems in the course of maintenance of drinking water facilities.

For example, water utilities need to periodically "de-water" their lines as part of routine maintenance. The de-watering of distribution lines transporting treating drinking water results in discharges containing trihalomethanes (THMs). The CTR proposes human health criteria for each of the four compounds comprising the THM classification. The total limit under the CTR for THMs as a group is 11 ug/L, sigficantly below the California SDWA MCL of 100 ug/L as well as the proposed level of 80 ug/L for Stage 1 of the Disinfection/Disinfectant By-Products Rule. Thus, the discharge of water that meets California SDWA standards could potentially violate CTR human health criteria if that water is discharged to a source of drinking water supply. Metropolitan requests that EPA establish CTR human health criteria for THMs consistent with the California SDWA MCLs for THMS.

Response to: CTR-025-003c

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a).

Comment ID: CTR-059-008
Comment Author: Los Angeles County Sanit. Dist
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-12a THMs Human Health
References: Letter CTR-059 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: Due to the time constraints of the comment period, we have focused our review and comments primarily on those criteria that we anticipate may cause compliance issues for one or more of the Sanitation Districts' WRPs (see below). Based on our initial review of the proposed rule, the Sanitation Districts recommend that adoption of some of the criteria be deferred. As explained in the attached comments, we believe that there are significant scientific issues regarding the human health criteria for several trihalomethanes that call into question the accuracy and appropriateness of the proposed criteria. In addition, we reconunend that EPA defer adoption of those criteria that are below detection limits and that have not been demonstrated to be adversely affecting water quality or the attaimnent of designated uses on a water body-specific basis in California. In addition, we recommend that EPA not adopt criteria for effluent dependent waters, unless they have been adjusted to reflect the characteristics of this type of water body.

Trihalomethanes Human Health Criteria

EPA has proposed human health criteria for consumption of water and organisms for four of the Trihalomethanes (THMs): bromofom (4.3 ug/L), Chlorodibromomethane (0.41 ug/L), Chloroform (5.7 ug/L), and Dichlorobromomethane (0.56 ug/L). We have a number of concerns about these criteria and recommend that EPA defer the adoption of these criteria or consider utilizing either the current or proposed drinking water standards in lieu of the proposed criteria.

First we can find no basis for the Bioconcentration Factor (BCF) fisted in the CTR Administrative Record Matrix (ARM), or in any of EPA's supporting documentation for the CTF, The ARM lists the BCF for chloroform as 3.75; the other three compounds have been assigned the sarne BCF "based on chloroform." We have been unable to determine the origins of the 3.75 BCF. The Administrative Record Matrix refers back to the 1980 Water Quality Criteria Document (WQCD).(*4) On page C-39 of the WQCD, EPA notes that

"Approximately 1 percent of the chloroform exposure results from the consumption of aquatic organisms which exhibit an average bioconcentration potential of 3.75-fold. The remaining 99 percent of chloroform exposure results from drinking water."

No further reference is provided for the derivation of the 3.75 bioconcentration factor.

Second, we do not believe that the four THMs bioaccumulate in fish tissue, EPA has established a policy for setting hunan health criteria in the Great Lakes Initiative whereby chemicals with half-lives less than eight weeks in water columns, sediments or biota are not bioaccumulative chemicals of concern (BCCs). Literature on chloroform indicates that it is non-persistent in water, with a half-life of less than two

days.(*5) Based on this finding, chloroform should not be considered as a BCC. This conclusion is supported by other information in the literature which shows that the THMs do not bioaccumulate in fish.(*6)(*7)(*8) Thus, the BCF of 3.75 used by EPA in calculating criteria for these four THMs is not a documented nor reasonable assumption for calculating human health criteria.

Third, similar to the situation with arsenic, EPA has different human health values for drinking water and for ambient water. The current drinking water MCL for the THMs is 100 ug/L with a proposed MCL of 80 ug/L. The proposed MCL was recently endorsed by EPA's Microbial/Disinfection By-Products Federal Advisory Committee as part of an Agreement in Principle, and will form the basis for the 1998 Enhanced Surface Water Treatment Rule. We believe that the application of the CTR criteria is inappropriate and potentially wasteful of the status resources if it causes POTWs to invest in treatment merely for treatment's sake. Thus, we recommend that EPA defer the adoption of these criteria or consider utilizing either the existing or proposed MCL in setting the human health criteria for the THMs in the CTR.

(*4) U.S. Environmental Protection Agency, Ambient Water Quality Criteria for Chloroform (EPA 440/5-80-033, October 1980).

(*5) Information obtained from University of Virginia, Office of Recycling and Environmental Information.

(*6) Oliver, B.G. and A.J. Niimi. "Bioconcentration Factors of Some Halogenated Organics for Rainbow Trout: Limitations in Their Use for Prediction of Environmental Residues." Environ. Sci Technol. 1985, 19,842-849.

(*7) Young, D.R., R.W. Gossett, R.B. Baird, D.A. Brown, P.A. Taylor and M.J. Miille. "Wastewater Inputs and Marine Bioaccumulation of Priority Pollutant Organics Off Southern California." Chapter 60 In Water Chlorination Environmental Impact and Health Effects. Ann Arbor Science Publishers, Inc., Ann Arbor Michigan, 1983.

(*8) Scott, G.I. "Physiological Effects of Chlorine-Produced Oxidants, Dechlorinated Effluents and Trihalomethanes on Marine Invertebrates." Chapter 57 In Water Chlorination Environmental Impact and Health Effects. Ann Arbor Science Publishers, Inc., Ann Arbor Michigan, 1983.

Response to: CTR-059-008

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to responses on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018. Regarding detection limit issues, refer to the response on effluent-dependent waters in CTR-034-007 and CTR 036-009.

The commenter is incorrect regarding the lack of documentation on the BCF for chloroform. The basis of the value of 3.75 is explained in the very document that the commenter claims it is lacking from. Using a documented BCF of 6 and an average lipid content of 4.8 percent from bluegills, EPA used a lipid adjustment factor based on the weighted average lipid percentage of 3 for the same freshwater and estuarine species that represent the fish consumption rate of 6.5 gm/day. Refer to text in EPA 440/5-80-033, October 1980, pp. C-3 and C-4).

However, EPA has decided to reserve the numeric criteria for chloroform in the final rule. EPA is

revisiting the cancer risk assessment for chloroform (see section G.6. of the preamble).

Comment ID: CTR-089-004
Comment Author: Las Virgenes Mncpl Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-12a THMs Human Health
References:
Attachments? N
CROSS REFERENCES

Comment: While the draft regulations demonstrate clear progress on these and other issues, there remain some unresolved problems that could compromise our ability to serve our customers. We offer these comments in the hope of minimizing those potential impacts.

Disinfection By-Products

Sanitation utilities may not be able to meet the proposed criteria for trihalomethanes (chloroform, dichlorobromomethane, chlorodibromomethane), which appear to be more stringent than those adopted for drinking water standards. Some consideration should be given to dischargers who must, by law, disinfect their effluent discharges, as the most widely-used disinfection method (oxidation by chlorine) unavoidably produces trihalomethanes. In addition, chlorine is an integral treatment process additive for control of filamentous algae in our activated sludge process and for operational control of our tertiary filtration process -- we simply must use this chemical to optimize process performance.

The proposed criteria imply a potentially enormous investment in alternative disinfection methods, or equally-expensive post-disinfection removal using carbon adsorption or air-stripping towers. Our preliminary estimate is that compliance with the proposed criteria for trihalomethanes would cost our served communities over $650,000 per year. Furthermore, the benefits of these expenditures are unclear, since neither drinking water supplies nor consumptive uses such as fishing are important uses of the receiving,waters.

Response to: CTR-089-004

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018.

Comment ID: CTR-090-022
Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-12a THMs Human Health

References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: Trihalomethanes (THM) - The current California Department of Health services criterion for Total THMs, is 100ug/L to be reduced to 80 ug/L in 1998. Chloroform is the dominant THM in drinking water and is a disinfection byproduct and is typically found in drinking water in the range of 34-45 ug/l. The proposed value under the CTR is 5.7 ug/L, which is two orders of magnitude below the chronic toxicity criterion and one order of magnitude below the California DHS standard for drinking water promulgated under the auspices of the Safe Drinking Water Act. Such a restrictive criterion will inhibit municipal water supply agencies in operation and maintenance of their water supply system. EPA needs to explain the rationale for such a restrictive criterion for THM.

Response to: CTR-090-022

EPA acknowledges that water quality criteria may be more stringent than drinking water MCLs and believes that this is appropriate (refer to response on this same issue in CTR-025-002a and CTR-025-003a). See also response to CTR-020-018. However, EPA has decided to reserve the numeric criteria for chloroform in the final rule. EPA is revisiting the cancer risk assessment for chloroform (see section G.6. of the preamble).